Field Safety Notice

Premature Battery Depletion with Implantable Cardioverter Defibrillator

Affected International Models can be found in the Appendix to this letter

11 October, 2016

Dear Customer,

We are advising you of a risk of premature battery depletion associated with St. Jude Medical ICD and CRT-D devices manufactured before May 23, 2015. Affected models include Fortify™, Fortify Assura™, Quadra Assura™, Quadra Assura MP™, Unify™, Unify Assura™ and Unify Quadra™.

Among 398,740 devices sold worldwide, 841 devices returned for analysis due to premature battery depletion have had evidence of lithium material in the form of "clusters" in the battery. Forty-six (46) exhibited visible clusters bridging the cathode and anode causing shorting. Lithium cluster formation is a known phenomenon with this type of battery.

We are contacting physicians to provide details regarding risk and patient management recommendations because premature battery depletion has been observed to occur within days. There have been 2 deaths that have been associated with the loss of defibrillation therapy as a result of premature battery depletion.

Mode and Identification of Premature Battery Failure

High voltage devices (ICDs and CRT-Ds) that utilize Lithium-based battery chemistries are subject to Lithium cluster formation during high voltage charging. Depending on their location, Lithium clusters may cause a short circuit that can lead to premature battery depletion. Our investigation indicates that if a short circuit occurs, battery depletion can occur in these devices within a day to a few weeks, which may result in the inability to deliver therapy.

Premature battery depletion can be identified by physicians through home monitoring or in person visits showing ERI or more advanced battery depletion. Patients may become aware when their device reaches ERI because they may feel a vibratory patient notifier alert. Patients who cannot feel the vibratory alert may not know their device has reached ERI. Therefore, we have provided recommendations below that include confirming patients can feel and recognize vibratory alerts and reaffirming the availability and usage of home monitoring to avoid or minimize time without device therapy for bradycardia and tachycardia events.

Estimation of Rate of Premature Battery Failure

A precise estimate of the rate of premature battery failure is difficult to obtain due to potential underreporting of battery depletion in general and battery depletion which may be due to this failure mode but not recognized.

841 returned devices (0.21%) of 398,740devices worldwide have premature depletion in association with lithium clusters. Forty-six (46) devices worldwide had visible electrical shorting due to lithium clusters. See Table 2 below for details.

At this time 349,852 affected devices are still in service worldwide and, therefore, potentially at risk.

Patient Management Recommendations

In consultation with our Medical Advisory Board, we recommend the following:

- **Do not implant unused affected devices.**
- **Conduct patient follow-up per standard practice.**
- **Prophylactic device replacement is NOT recommended** because complications following replacement have been reported to occur at a greater rate than the rate of harm associated with premature battery depletion due to lithium cluster induced shorts (see appendix for selected references).
- **In the event of an ERI indicator in these devices, immediate device change is recommended.** At this time there is no factor, method or test to identify devices with this form of premature battery depletion approaching ERI or to accurately predict remaining battery life once ERI appears.
- Physicians should reaffirm the availability of home monitoring to avoid or minimize time without device therapy for bradycardia and tachycardia events.
- **Enroll patients in Merlin.net utilizing the "Direct Alerts" feature** to provide you with an immediate alert notification in the event ERI is reached. For patients currently enrolled in Merlin.net, remind them of the importance of using remote monitoring.
- **Review the most recent Programmed Parameters printout (**see attached for an example).
  - Ensure that under the **"Trigger Alerts When"** section, that the **"Device at ERI" parameter is ON** (it is normally ON) for both "Show on FastPath" and "Notify Patient" selections.
  - If the "Device at ERI" alert is OFF, we recommend that the patient be seen promptly to program this parameter ON.
- **Advise patients that an ERI indication triggers a vibratory alert.** At the next scheduled office visit:
  - Interrogate the patient's device to determine if an ERI alert has been triggered. Premature battery depletion can be identified by physicians through home monitoring showing ERI or more advanced battery depletion.
  - Perform a patient notifier test to confirm that the patient feels and recognizes the vibratory alert.
  - Patients who cannot feel the vibratory alert may experience loss of battery and/or loss of device function without their awareness.
  - **Advise the patient to contact your office promptly should they feel a vibratory alert.**
    - In-office evaluation should be performed to determine the reason for the alert as other non-critical events can also trigger a vibratory alert.

We recognize that individual patients may require unique clinical considerations. If the decision is made to replace an affected device for individual patient circumstances, St. Jude Medical will provide a replacement device at no cost. Please return any explanted devices to SJM for further evaluation.

Should you have questions about patient management, including observed changes in battery longevity, please contact your local Sales Representative or St. Jude Medical Technical Services at +46-8474-4147, which is available 24 hours a day, 7 days a week.

Your St. Jude Medical representative will replace any affected inventory you may have at your center(s). To determine if a device serial number is subject to this advisory, please go to the following website: www.sjm.com/batteryadvisory

We apologize for any difficulties this causes you and your patients.

Sincerely,

[redacted]

Attachments

APPENDIX

Table 1 – O.U.S. Models

Model	Trade Name	Model	Trade Name	Model	Trade Name	Model	Trade Name
CD1233-40	Fortify™ VR	CD2233-40Q	Fortify™ DR	CD3251-40	Unify Quadra™	CD3361-40C	Unify Assura™
CD1233-40Q		CD2235-40	Fortify™ ST DR	CD3251-40Q		CD3361-40Q	
CD1235-40	Fortify™ ST VR	CD2235-40Q		CD3255-40	Unify Quadra MP™	CD3361-40QC	
CD1235-40Q		CD2259-40	Fortify Assura™ DR	CD3255-40Q		CD3367-40	Quadra Assura™
CD1259-40	Fortify Assura™ VR	CD2259-40Q		CD3261-40	Unify Assura™	CD3367-40C	
CD1259-40Q		CD2299-40	HeartMinder™ ST DR	CD3261-40Q		CD3367-40Q	
CD1299-40	HeartMinder™ ST VR	CD2299-40Q		CD3267-40	Quadra Assura™	CD3367-40QC	
CD1299-40Q		CD2359-40	Fortify Assura™ DR	CD3267-40Q		CD3371-40	Quadra Assura MP™
CD1359-40	Fortify Assura™ VR	CD2359-40C		CD3271-40	Quadra Assura MP™	CD3371-40C	
CD1359-40C		CD2359-40Q		CD3271-40Q		CD3371-40Q	
CD1359-40Q		CD2359-40QC		CD3281-40	Excelis Quadra™	CD3371-40QC	
CD1359-40QC		CD2391-40C	HeartMinder™ + DR	CD3281-40Q		CD3385-40C	Quadra + Excelis™
CD1391-40C	HeartMinder™ + VR	CD2391-40QC		CD3297-40	Excelis™ CRT-D	CD3385-40QC	
CD1391-40QC		CD3235-40	Unify™	CD3297-40Q		CD3389-40C	Excelis™ +
CD2233-40	Fortify™ DR	CD3235-40Q		CD3361-40	Unify Assura™	CD3389-40QC	

Table 2 – Rates

The table below summarizes the worldwide experience for the affected devices that were returned for product analysis due to premature battery depletion. In these 841 devices, 46 batteries had confirmed shorts due to Lithium clusters that bridged the battery's cathode and anode. In the remaining 795 devices a battery short was not confirmed by returned product analysis, but the presence of Lithium clusters was noted during battery analysis and no other cause for premature battery depletion was identified. Therefore, we have included both confirmed and unconfirmed shorts in the rate table below to help you assess the risk to your patients:

Patient Impact	Confirmed Shorts / Rate	Unconfirmed Shorts / Rate	Total / Rate
Additional Surgery Only	46 / 0.012%	746 / 0.187%	792 / 0.199%
Loss of Pacing – Minor (Dizziness)	0 / 0.000%	37 / 0.009%	37 / 0.009%
Loss of Pacing – Major (Syncope)	0 / 0.000%	10 / 0.0025%	10 / 0.0025%
Loss of Defibrillation - Death	0 / 0.000%	2 / 0.0005%	2 / 0.0005%
Total	46 / 0.0115%	795 / 0.199%	841 / 0.211%

Device Replacement Complication Publications

1) John W. Moore III, William Barrington, et. al.; "Complications of replacing implantable devices in response to advisories: A single center experience"; International Journal of Cardiology 134 (2009) 42–46 **(5.5% overall, 2.1% major complications)**

2) Paul A. Gould, MBBS, PhD, Lorne J. Gula, MD, et. al.; "Outcome of advisory implantable cardioverter-defibrillator replacement: One-year follow-up"; Heart Rhythm, Vol 5, No 12, December 2008
(9.1% overall, 5.9% major complications, including two deaths)

3) Krystina B. Lewis, Dawn Stacey, R.N., Ph.D, et. al.; "Estimating the Risks and Benefits of Implantable Cardioverter Defibrillator Generator Replacement: A Systematic Review; PACE, Vol. 39, July 2016
(7.5% overall, 4.0% major complications)